UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.* DAVID M. KESTER, *et al.*, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION, Defendants.	Civil Action No. 1:11-cv-08196-CM

CVS CAREMARK CORPORATION'S
REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

INTRODUCTION

Relator's Opposition brief confirms what is really going on in this case. Relator has no real information about any supposed misconduct by CVS Caremark—as the Complaint makes clear, he personally was exposed to none in his work for Novartis. Instead, Relator seeks to capitalize on general allegations of abuse against the specialty pharmacy industry. He hopes that by making these general allegations, he can get discovery from CVS Caremark and unearth evidence that would allow him to profit as a *qui tam* relator. While this unfortunately is not an uncommon strategy, it is not how the *qui tam* process is supposed to work. Rather, like any federal lawsuit, a *qui tam* complaint can survive only if it alleges plausible facts with the level of specificity—here, the level prescribed by Rules 8(a) and 9(b)—required to state a claim.

Relator's claim against CVS Caremark is not plausible. It presumes that CVS Caremark accepted rebates from Novartis, not for the altogether proper purposes that make rebates commonplace in the industry, but in exchange for pushing Novartis medications on patients who did not need them. As Relator concedes, however, pharmacists have *no authority to prescribe these medications*, and the doctors who *do* have such authority are not alleged to be involved in the scheme. Relator's Opposition alleges no specific facts about CVS Caremark, or any doctors who were persuaded by pharmacists to abandon their independent medical judgment and prescribe Novartis products, or any patients who were persuaded to fill or refill those prescriptions with CVS Caremark. In other words, it offers no facts that could transform Relator's claim from head-scratching to plausible, much less particular. Relator's Complaint is a theory in search of a case, and the theory makes no sense.

The Complaint should be dismissed for other reasons as well. The Court lacks jurisdiction to consider the merits of the Complaint because it is based on information in the

public domain. Specifically, Relator's allegations mirror those in multiple prior state government proceedings against CVS Caremark, which were widely reported in the press. Relator quibbles that his Complaint offers some additional details, but he cannot seriously dispute that his allegations are "substantially similar" to the claims in those prior proceedings which, like his Complaint, alleged that CVS Caremark accepted performance-based financial rewards from pharmaceutical companies in exchange for efforts to switch patients to their medications and increase sales. Substantial similarity is all that the FCA's Public Disclosure Bar requires. Relator's alternative claim that he is an "original source" of the information, and thus exempt from the Public Disclosure Bar, is utter fantasy: Relator has no personal knowledge about any alleged fraud by CVS Caremark, or involving the three drugs (Gleevec, Tasigna, and TOBI) for which he has sued CVS Caremark.

Finally, as a pure legal matter, a substantial part of Relator's case should be dismissed because he has not alleged that any claims submitted by CVS Caremark prior to March 23, 2010 were legally false. Relator agrees that falsity for FCA purposes requires a showing that CVS made a false certification to the government. He rightly abandons any claim that CVS Caremark made an express certification. Instead, Relator charges that whenever it submitted a prescription for reimbursement, CVS Caremark *impliedly* certified to the government that it had complied with the Medicare-Medicaid Anti-Kickback Statute ("AKS"). The Second Circuit's controlling *Mikes* case flatly defeats this theory because the AKS until March 23, 2010 did not expressly condition reimbursement on compliance. Relator has no answer to *Mikes*; he asks the Court to disavow *Mikes* and follow decisions from other Circuits that overtly disagree with the Second. That is a non-starter. While the entire Complaint should be dismissed for the reasons

summarized above, at a minimum the Court should dismiss the Complaint insofar as it is predicated on claims submitted for reimbursement before the March 23, 2010 AKS amendment.

ARGUMENT

I. THE PUBLIC DISCLOSURE BAR DIVESTS THE COURT OF JURISDICTION TO CONSIDER RELATOR'S CLAIMS.

Relator's allegations against CVS Caremark are "substantially similar" to those raised years ago, in proceedings brought against CVS Caremark by multiple state governments and in many press reports. The Public Disclosure Bar thus applies here. Relator's arguments to the contrary fundamentally misconstrue both the prior proceedings and his own Complaint.

Relator first suggests that the prior proceedings did not disclose the "critical elements" of the fraud he alleges. Opp. at 13. In fact, what he now calls missing "critical elements" are merely supporting details. It is well settled that the Public Disclosure Bar does not demand prior disclosure of every fact a relator alleges. "The question . . . is whether the information conveyed [to the government] could have formed the basis for a governmental decision on prosecution, or could at least have alerted law-enforcement authorities to the likelihood of wrongdoing." *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 298 (S.D.N.Y. 2013) (alteration in original) (internal quotation marks omitted).

That test is amply satisfied here. The state proceedings occasioned the disclosure of extensive allegations that CVS Caremark was compensated by pharmaceutical manufacturers with discounts and rebates tied to performance metrics (including "market share" or "performance rebates"), and that it contemplated switching patients to new medications in exchange for such compensation, allegedly without disclosing those rebates. CVS Caremark Mem. at 10-13. The state complaints specifically alleged, for example, that Caremark was paid to distribute "'information and marketing materials to physicians and [patients] to promote

particular drugs to those physicians and [patients].'" *Id.* at 11 (quoting Complaint, *Cox ex rel. Michigan v. Caremark Rx, LLC*, No. 08-187-CP (Mich. Cir. Ct., Ingham Cnty. Feb. 13, 2008) (Ex. A to CVS Caremark Mem.)). These litigations concluded with a broad Consent Decree that covered this alleged conduct. *See* Final Judgment and Consent Degree, *Cox ex rel. Michigan v. Caremark Rx, LLC*, No. 08-187-CP, at 47 (Mich. Cir. Ct., Ingham Cnty. Feb. 13, 2008) (Ex. C to CVS Caremark Mem.). The prior allegations were sufficient to put the government on notice that CVS Caremark might be accepting performance incentives from manufacturers for inducing drug switching and refills through its specialty pharmacy operations.[1]

Relator argues that the prior proceedings did not specifically identify Novartis or the three particular Novartis drugs in this case. That is legally irrelevant because the state proceedings *did* explicitly identify CVS Caremark as a defendant in the fraud involving an identifiable class of manufacturers (inclusive of Novartis) and drugs (inclusive of Gleevec, Tasigna, and TOBI). *See U.S. ex rel. Morgan v. Express Scripts, Inc.*, No. 2:05-cv-1714 (DMC) (JAD), 2013 WL 6447846, at *12 (D.N.J. Dec. 9, 2013) (reasoning that where a defendant is identifiable within a class, "the prior public disclosure is valid as to that Defendant").

Relator also points to other "critical elements" that he perceives to be missing from the state actions: a longer time period of wrongdoing, overlapping with the time period of the state proceedings but continuing after they concluded; and "inducements in the form of entry into an exclusive distribution network and patient referrals." Opp. at 13. Again, these details do not

[1] Relator suggests that by referencing the prior state proceedings, CVS Caremark is somehow admitting that it engaged in prohibited practices. Opp. at 13. Obviously, that is wrong. CVS Caremark admitted no wrongdoing whatsoever in resolving the state actions; the performance rebates at issue were and are both customary and lawful, and CVS Caremark was allowed to continue accepting them under the Consent Decree. *See* CVS Caremark Mem. at 12-13; Consent Decree at 16-17. CVS Caremark need not admit Relator's *allegations* to demonstrate that they are substantially similar to the *allegations* in the prior proceedings.

negate the prior public disclosures, which were more than sufficient to place the government on notice of the same alleged course of conduct. Far from requiring complete temporal or substantive congruity, the public disclosure bar prohibits "even those *qui tam* complaints which are based only *in part* upon public disclosures." *U.S. ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 572 (10th Cir. 1995); *accord U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 453 (S.D.N.Y. 2001). Relator does not dispute, because he cannot, that he is alleging a scheme by CVS Caremark to receive "cash payments styled as 'performance rebates' or 'performance discounts' [] for recommending to patients, physicians, and other healthcare managers the ordering or refilling of Novartis medications," Compl. ¶ 52, precisely the type of manufacturer payments at issue in the state actions, *see* CVS Caremark Mem. at 10-13.

Relator's argument that he is exempt from the Public Disclosure Bar as an "original source" of the information in his Complaint is equally meritless. To give the false impression of some personal involvement, his Opposition brief recites that he "reviewed" documents and "attended" presentations "that specifically addressed the Gleevec/Tasigna transactions." Opp. at 15 (citing Compl. ¶¶ 86-89, 93, 95). *But that is not what the Complaint says*—the paragraphs he cites do not even allege that Relator had personal knowledge that the documents and presentations existed. His purported connections to TOBI are equally tenuous: Relator points to a business plan that was supposedly "made available to [him]." *Id.* (citing Compl. ¶ 106). *But that contention is not in the Complaint*, and in any event, he doesn't even suggest that he actually ever reviewed this alleged document.

A fair reading of the Complaint in fact reveals that the Relator had *no* involvement whatsoever with CVS Caremark, *no* involvement whatsoever with Gleevec and Tasigna prior to filing the Complaint, and *no* knowledge of the alleged TOBI initiative beyond a few secondhand

meetings and phone calls. He does not have the "direct and independent knowledge" of fraud that the "original source" exception requires. *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995) (per curiam); *see also U.S. ex rel. Feldstein v. Organon, Inc.*, 364 F. App'x 738, 743 (3d Cir. 2010) (relator is not original source in *qui tam* where "he describe[d] no fraud concerning [the drug] that he personally witnessed or in which he participated").

II. THE ALLEGED FRAUD IS NEITHER PLAUSIBLE NOR PLED WITH PARTICULARITY.

A. Relator's Theory Is Not Plausible.

Relator contends that his Complaint is "more than plausibl[e]," even though its theory is that Novartis paid CVS Caremark and other specialty pharmacies to increase sales of prescription medications without any involvement by the prescribing physicians. Relator concedes that, with respect to every single claim CVS Caremark submitted for reimbursement to a government payor: (1) the medication or refill was actually prescribed to the patient by a doctor, and (2) he has not alleged that a doctor was improperly paid or induced to write the prescription. By definition, therefore, every claim for reimbursement that CVS Caremark submitted was the product of a doctor's independent and untainted professional judgment to prescribe the drug to a patient. To assert a plausible claim, therefore, Relator at a minimum would have to allege facts showing that CVS Caremark accepted rebates for an improper purpose of inducing Novartis prescriptions—prescriptions that CVS Caremark had no authority to write—instead of for the much more logical and entirely proper purposes for which rebates are commonly paid in the industry. *See* CVS Caremark Mem. at 13 (describing these practices).

Relator's responses are unconvincing in the extreme. First, he argues that the AKS prohibits improper payments to "any person," not just doctors. Opp. at 23. That is true, but it begs the question of whether the payments are improper in the first place. It is one thing to

allege that a payment to a pharmacist is an improper inducement when the pharmacist actually has decision-making authority that can be corrupted. It is quite another thing to allege that a payment to a pharmacist was made with the requisite culpable intent to induce improper prescriptions when the pharmacist had no authority to prescribe the medication. Such allegations simply are not plausible. *See* Mar. 14, 2014 Hr'g Tr. 36:14-15 (THE COURT: "I don't understand how the pharmacy/patient relationship could have resulted in the writing of a prescription . . . ."). This is precisely the distinction the Fifth Circuit made in *United States v. Miles*, where it rejected the government's claim of an AKS violation because "the payments . . . were not made to the relevant decisionmaker as an inducement or kickback [for referrals]." 360 F.3d 472, 480 (5th Cir. 2004).

Second, Relator argues that the Court should disregard the physicians' role because "*a patient* must order refills for the drug." Opp. at 26. This ignores the undisputed fact that a pharmacist cannot refill a prescription unless *the doctor* has made an independent and untainted judgment that the refill *for that drug* is medically appropriate. Here again, the only support Relator offers are general allegations that have *nothing to do with CVS Caremark*. Opp. at 26-27 (repeating allegations against BioScrip involving Exjade).

Third, Relator argues that pharmacists actually influence physicians to prescribe drugs to patients, Opp. at 27-28, implying that CVS Caremark was paid to persuade doctors to make decisions about their patients' medical care that they would not otherwise have made. That suggestion is counter-intuitive, to say the least, and the Complaint does not plausibly support it. Certainly the Complaint does not allege any *facts*, as opposed to conclusions, that would show that any doctor's independent medical judgment was somehow impaired because a pharmacist suggested that the doctor should prescribe Gleevec, Tasigna or TOBI. "[G]eneral statistics" are

no substitute for actual, "plausible allegation[s]" that doctors wrote corrupt prescriptions. *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 459 (4th Cir. 2013).

B. The Complaint Does Not Plead Fraud With Particularity.

Relator's theories simply do not make sense; they do not state a plausible claim for relief as a matter of fact or law. This lack of plausibility is closely tied to the other fundamental problem with the Complaint: it fails to particularize any allegations against CVS Caremark. As discussed in detail in CVS Caremark's separate letter-submission concerning Rule 9(b), the Complaint alleges *none* of the elements of an FCA claim with particularity. *See U.S. ex rel. Woods v. Empire Blue Cross & Blue Shield*, No. 99 CIV. 4968, 2002 WL 1905899, at *4 (S.D.N.Y. Aug. 19, 2002) (internal quotation marks omitted) (complaint must allege the "who, what, when, where and how of the alleged fraud").

The Complaint's generic allegations against CVS Caremark do not come close to satisfying this standard. The Complaint does not allege, for example, any actual false claims, *who* at CVS Caremark made such claims, *when* they were made, *how* or *why* they were false, or that anyone at CVS Caremark had the requisite culpable mental state. *See* Mar. 21, 2014 CVS Caremark 9(b) Letter (Dkt. No. 165). Indeed, the Complaint does not identify by name or by title a single CVS Caremark employee, nor does it provide a single date or other detail as to when, where or how CVS Caremark allegedly entered into the fraudulent scheme. Particularly in the absence of these required details, it is impossible to conclude that CVS Caremark received payments for a corrupt purpose (let alone a plausible one) that the AKS forbids.

III. RELATOR'S PRE-MARCH 23, 2010 CLAIMS SHOULD BE DISMISSED BECAUSE THE COMPLAINT DOES NOT PLEAD A FALSE CERTIFICATION.

Relator concedes that he cannot recover under the FCA for any claims submitted before March 23, 2010 unless he can show that CVS Caremark falsely certified its compliance with the

AKS. In his Opposition brief, Relator abandons any argument that CVS Caremark made an "express" certification, and instead contends only that he has adequately alleged an *implied* false certification. Opp. at 17. He has not. Under governing Second Circuit law, an implied FCA certification occurs only when the "underlying statute or regulation" (here the AKS) "*expressly* states the provider must comply in order to be paid." *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001). Relator does not even attempt to argue that the AKS or any of its implementing regulations contained such an "express" instruction prior to March 23, 2010, and accordingly his claims based on conduct prior to that date should be dismissed.[2]

Relator's Opposition effectively asks this Court to abandon the Second Circuit's clear implied certification rule in favor of less restrictive decisions from other jurisdictions. Citing those cases, Relator misleadingly suggests that "[i]t is well-settled law that compliance with the AKS is a condition of payment for Medicare." Opp. at 18. But the Second Circuit has specifically held that the FCA requires more: an *express* statement in the underlying statute or regulation. In fact, Relator cites as his leading authority a First Circuit case that *explicitly rejected the Second Circuit's standard*. *See U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 386-87 (1st Cir. 2011) (writing that it is "not bound by" *Mikes* and "reject[ing] both requirements" that "implied conditions of payment can only be found in statutes and regulations, and that these sources must expressly state the obligation"). Applying the governing *Mikes* test, it is beyond dispute that, until March 23, 2010, the AKS did not "*expressly*" make compliance a

[2] *Mikes* applies with equal weight to Relator's state Medicaid claims, and Relator has similarly failed to identify any *express* prerequisite for the vast majority of those state programs. *See* Accredo and Curascript Mem. at 15-17 (Dkt. No. 178).

condition of payment. *Mikes*, 274 F.3d at 700. Courts that have considered *that* question have so held.[3]

Relator also argues that the Court should apply the March 23, 2010 AKS amendment retroactively, to govern pre-amendment conduct. Op. at 20-22. But the amendment "makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates [a] claimed defense to a *qui tam* suit." *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010); *see also U.S. ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 895 F. Supp. 2d 872, 881 (N.D. Ill. 2012) (holding that the AKS amendment cannot be applied retroactively to support an implied certification theory of liability).

The Second Circuit's test could not be clearer. In the absence of an "underlying statute or regulation" that "*expressly* state[d] the provider must comply [with the AKS] in order to be paid," *Mikes*, 274 F.3d at 700, Relator cannot recover under the FCA for any claims submitted before March 23, 2010.

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed with prejudice.

---

[3] *See, e.g.*, *U.S. ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009) ("The Court agrees with the Second Circuit, however, that this [implied certification] theory is viable in the Medicare context only when the underlying statute upon which the FCA relator relies *expressly* states that the provider must comply in order to be paid. That is not true of the anti-kickback statute.") (citation omitted); *Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, No. 00-CV-4863, 2003 U.S. Dist. LEXIS 27469 at *23 (E.D. Pa. Aug. 14, 2003) ("Applying the limitation of the implied certification theory advanced by the Second Circuit in *Mikes*, this Court finds that FCA liability cannot be based on 'implied certifications' of compliance with the Anti-Kickback Statute, because the Anti-Kickback Statute itself does not expressly state that a provider must comply with the statute in order to be paid.") (citation omitted) (attached as Ex. A); *see also U.S. ex rel. Barmak v. Sutter Corp.*, No. 95 CIV. 7637 KTD RLE, 2002 WL 987109, at *5 (S.D.N.Y. May 14, 2002) (in a case predating the AKS amendment, skeptically questioning whether the FCA may be used "as a vehicle for pursuing a violation of the anti-kickback statute in this Circuit").

Dated: June 4, 2014

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

By: /s/ Enu Mainigi

Enu Mainigi (admitted *pro hac vice*)
Amanda M. MacDonald (admitted *pro hac vice*)
Nicholas G. Gamse (admitted *pro hac vice*)

725 Twelfth Street, N.W.
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for CVS Caremark Corporation